Specialty Pharmacy Accreditation

Version 5.0
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URAC
1220 L Street, NW, Suite 900
Washington, DC 20005
Phone: (202) 216-9010
Fax: (202) 216-9006
www.urac.org

Terms listed within Specialty Pharmacy Accreditation, v. 5.0 are referenced in the URAC Program Glossary 2022 Version.

Message from Shawn Griffin, MD, URAC President & CEO

Dear Applicant,

As health care evolves, URAC's commitment to consumer safety and empowerment drives us to continually update our portfolio of recognition programs. Everything we do – every standard we promote – seeks to improve the quality of health care delivered to patients.

The URAC seal marks an organization as going beyond regulatory compliance in its health care-related operations and represents its commitment to excellence in its services to purchasers, patients, providers and other stakeholders.

URAC thanks those health care stakeholders who volunteered to revise the Specialty Pharmacy v. 5.0 Accreditation program, including the URAC Board of Directors, URAC Health Standards Committee, URAC Pharmacy Advisory Council, and expert panel members.

On behalf of the URAC Team, I invite you to take advantage of the companion tools available to you as part of your accreditation:

- URAC's Client Portal
- www.urac.org
- AccreditNet® General Resources
- URAC publications
- Educational offerings – online/offline

Should you desire more information, please contact your Client Relations Manager. We wish you and your organization success as you work through the recognition process.

Respectfully yours,

Shawn Griffin, MD

URAC Recognition Programs

Recognition programs, such as accreditations, certifications and designations, signify that an organization is committed to quality management principles.

URAC Recognition Program Review Process

The following figure highlights the key steps that take place in URAC's accreditation and certification process. We encourage you to work closely with your Client Relations Manager and assigned Reviewer to ensure your organization is proceeding through the process as expected.

For more information about URAC's review process, please go to urac.org/ or your Client Portal.

Compliance with Jurisdictional Law

URAC expects that the applicant will comply with all applicable laws and regulations. Jurisdictional laws and regulations supersede URAC standards if the laws or regulations are more rigorous than URAC standards. Conversely, an applicant must comply with URAC standards if the standards are more stringent, or when they result in a clear benefit to the health care consumer. If an applicant is required by law or regulation to carry out its business in a manner not consistent with URAC standards, then the applicant may request a variance.

Exceptions to Standards Compliance

Some standards and elements of performance may not be applicable to an applicant organization. The applicant may indicate this when submitting their application to URAC. Mandatory Standards, however, cannot be designated as "Not Applicable", as described in the following section. A final determination about the applicability of a standard or element of performance to an applicant will be made during the review process by the URAC Committees that have final authority for recognition program decisions.

Scoring Description

URAC's programs utilize three types of scores. Each type, listed below, includes its abbreviation in parentheses and a description of its major features.

Mandatory Standards ([M]): Assessed at the Standard level, Mandatory criteria must be met for an applicant to achieve recognition. Failure to meet Mandatory criteria may result in Recommendation of Denial to URAC's Accreditation Committee. No numeric score is assigned. These Standards may not be designated as "Not Applicable."

Weighted Elements / Sub-Elements of Performance: Assessed at the element and/or sub-element of performance levels, criteria are assigned numeric weights. Points earned, as demonstrated by compliance, contribute to the overall score of the recognition program. These criteria may be designated as "Not Applicable" by an applicant. If URAC agrees, the points do not count against the applicant's overall score (i.e., they are removed from the denominator).

Leading Indicator ([L]): Assessed at the Standard, element and/or sub-element of performance levels, Leading Indicators are optional and are not included in scoring. These criteria may be designated as "Not Applicable" by an applicant. Compliance is recognized on an organization's Accreditation, Certification or Designation Summary Report when a decision is rendered.

Determining a Recognition Program Score

Compliance Ratings

- For all items, a rating of "Met" or "Not Met" is applied.
- No credit is given for partial compliance.
- Even when full accreditation or certification is achieved, some elements that are identified as "Not Met" will trigger a follow up review within 6 months to verify full compliance. Please review the interpretive information in the guide for further information on which elements will require a follow up review.
- Regarding items for which an audit is necessitated, the following thresholds on audit performance apply to the determination of "Met."
  - Weighted [2] and [4] Standards: For all file types, an audit score of ≥ 80%.
  - Mandatory and Weighted [8] Standards: For all file types, an audit score of ≥ 90%.

Assessing Mandatory Requirements

- As stated previously, Mandatory requirements are assessed at the Standard level. All items must be met for the Mandatory Standard to be met.
- Any Mandatory Standard found to be "Not Met" may result in Recommendation of Denial to URAC's Accreditation Committee.

Determining a Weighted Score

- URAC uses a roll-up methodology for determination of an overall weighted score.
  - Scoring a Group of Elements of Performance:
    - Weighted sub-elements (i, ii, iii, etc.) average to the element (a, b, c, etc.) level
    - Weighted elements (a, b, c, etc.) average to the group of elements level (1-1, 1-2, 1-3, etc.)
  - Total Possible Points (Denominator): Sum of points possible for each group of elements.
  - Total Accumulated Points (Numerator): Sum of points earned for each group of elements
- Scoring a multi-site accreditation or certification: The lowest rating for a Standard, Element, or Sub-Element across sites where a validation review has been conducted is used to calculate the total score for the application.

Review Period (also known as the "look-back" period)

For initial applications, the review period generally begins from the date an organization submits an application to URAC for the first time for a given accreditation or certification program. For reaccreditation and recertification applications, the review period generally begins from the effective date of an organization's current accreditation or certification.

Decision Levels for URAC Recognition Programs

Decision Levels for Accreditation Programs

URAC's Accreditation Committee determines accreditation status using the following guidelines.

STATUS*	MANDATORY STANDARDS	WEIGHTED EPs/Sub-EPs
FULL / PROVISIONAL**	The Mandatory standards are met and	Score of ≥ 94%
CONDITIONAL		Score of ≥ 90%, but < 94%
CORRECTIVE ACTION		Score of ≥ 85%, but < 90%
DENIAL	The Mandatory standards are not met and/or	Score of < 85%

*For those statuses listed, only Full, Provisional, and Conditional are considered Accreditation awards. As such, these are the only accreditation decisions that are displayed on URAC's Directory of Accredited Organizations.

**Provisional Accreditation applies to those organizations that have not yet begun business operations but reflect compliance with URAC's criteria through Desktop Review.

Decision Levels for Designation Programs and Supplemental Government Requirements

URAC's Accreditation Committee determines designation status using the following guidelines. Note that designations and supplemental government requirements do not have conditional or corrective action status.

STATUS*	MANDATORY STANDARDS
FULL	All Mandatory standards are met
DENIAL	One or more Mandatory standards are not met

*Only Full designation decisions and only Full supplemental government requirements decisions are displayed on URAC's Directory of Accredited or Certified Organizations.

Follow Up Validation Reviews

Some organizations require additional opportunities to demonstrate full compliance with elements of performance. Corrective action and a follow up review may be required for accreditation and/or certification applicants who reach a status of Full, Conditional, or Corrective Action. Opportunities for improvement are not available to designation or supplemental government requirement applicants. When a follow up review is required, the organization will be provided a six-month period, as appropriate to the program. Within that time frame, the organization must demonstrate compliance with the identified areas of non-compliance. An organization may request an additional six months from the Accreditation Committee, as appropriate to the program, and may be granted an additional six-months. Clients who are unable to demonstrate compliance after two six-month periods may receive a denial.

An applicant that falls into a denial status must submit a new application if they intend to pursue accreditation again. Denial of accreditation, certification, designation, or supplemental government requirements guidelines are found in the URAC Accreditation Application Agreement (AAA) or Certification Application Agreement (CAA).

Note on Protected Health Information (PHI) and Individually-Identifiable Health Information (IIHI)

Please do not submit documents containing protected health information (PHI) or individually-identifiable health information (IIHI) to URAC. Applicants upload documents in AccreditNet® as part of the application submitted to URAC, and these documents are used to demonstrate compliance with the standards and elements of performance. None of the documents should contain any PHI or IIHI.

Disclaimer

This document has been provided for information purposes only and is not intended, and should not be construed, to constitute legal advice. Furthermore, this document and the proposals contained herein have not been approved by any regulatory body unless explicitly stated. While preparing this document, URAC has reviewed the available guidance. The organization seeking accreditation, certification or designation should consider any guidance that may have become available since the issuance of this document, including any guidance from applicable regulators. If you have any questions, please contact URAC by phone at 202-216-9010, by email at businessdevelopment@urac.org, or visit our website at www.urac.org.

Specialty Pharmacy Accreditation Program Information

URAC revised the Specialty Pharmacy program to offer independent third-party validation of specialty pharmacy processes, including dispensing, medication distribution, and patient management. Specialty Pharmacy Accreditation positions eligible organizations to demonstrate to their current and prospective business partners and/or stakeholders their commitment to high performance through elective, independent validation that quality management principles are embedded in their daily operations.

The accreditation process encourages organizations to review and confirm their operational soundness, set priorities, drive organizational improvements, and build strong processes. Achievement of the Specialty Pharmacy Accreditation publicly demonstrates the organization's commitment to quality and competitively positions organizations in their business-to-business endeavors.

Focus Area: Risk Management (RM)

Standard RM 1: Regulatory Compliance and Internal Controls

The organization promotes compliance with applicable jurisdictional laws and regulations. [M]

RM 1-1: Regulatory Compliance Management

The organization:

a. Tracks applicable jurisdictional laws and regulations

b. Audits compliance with applicable jurisdictional laws and regulations

c. Responds to detected risks, problems and incidents related to regulatory compliance and takes appropriate action to prevent future occurrences

d. Identifies a Compliance Officer responsible for overseeing the Compliance Program

Interpretive Information

- (a)-(b) The organization is responsible for tracking and auditing laws and regulations in any jurisdiction where compliance is required to do business.
- (d) The compliance officer position may be a full-time position or integrated within a broader position.

Demonstrating Compliance: Desktop Review

- (a)-(c) Regulatory compliance document(s) describing the organization's regulatory compliance processes.
- (a) Evidence of the tracking mechanism used.
- (b) Evidence of audit(s).
- (d) A job description for the compliance officer or the job description(s) that include the compliance officer roles and responsibilities.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

Standard RM 2: Regulatory Compliance

The organization maintains compliance with applicable jurisdictional laws and regulations.

RM 2-1: Maintaining Compliance

The organization:

a. Maintains compliance with all applicable jurisdictional laws, regulations and requirements not otherwise addressed by the program standards [8]

Interpretive Information

- (a) Organization remains in good standing with any issuing body/ agency for all permits, licenses, registrations and/or charters held by the organization.
- (a) The organization is responsible for maintaining compliance with laws and regulations in any jurisdiction where compliance is required to do business.
- Even when full accreditation or certification is achieved, if this standard is identified as "Not Met," a follow-up validation review will occur within six (6) months to verify full compliance.

Demonstrating Compliance: Desktop Review

- (a) An attestation confirming the organization maintains compliance with applicable jurisdictional laws, regulations and requirements.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

Standard RM 3: Information Systems

The organization promotes information system maintenance and security through prevention and risk assessments.

RM 3-1: Information Systems Management

The organization:

a. Provides for data integrity of information systems [8]

b. Implements a plan for storage, maintenance and destruction of information [8]

c. Implements strategies to mitigate threats to privacy of information systems data in transit and at rest, including encryption, at a minimum [8]

Interpretive Information

- Information and systems cover at a minimum electronic and any paper data.
- Information system management includes any location where data may be used, including in office or a remote location.
- (a) "Data integrity" means data accuracy and traceability.
- (a) Examples include monitoring data entry for personnel accuracy, cross-checking databases for consistency, using unique identifiers for data, prevention of and checking for duplicate entries, etc.
- (b) A plan for storage, maintenance and destruction includes information location and retrieval, accountabilities for stored information, who has and approves access, how long information is maintained before it is destroyed and how it will be destroyed.
- (b) Destruction processes should include data destruction for discarded or unused terminals, personal computers and portable media devices.

Demonstrating Compliance: Desktop Review

- (a) Information system document(s) outlining how the organization provides for data integrity.
- (b) Information system document(s) outlining how information is stored, maintained and destroyed.
- (c) Information system document(s) outlining strategies to mitigate threats to privacy of information systems.

Demonstrating Compliance: Validation Review

- (a)-(c) Interview with responsible individuals (i.e., IT, compliance, risk manager).

RM 3-2: Systems Risk Assessment

The organization:

a. Maintains a risk assessment process, which includes: [4]
    i. Periodic risk assessments of information systems
    ii. Corrective action(s), if applicable, based on findings from the risk assessment

Interpretive Information

- (a)(i) Define when a risk assessment is conducted based on criteria such as an implementation of a new system, change in location and reassessments to implement updated technology.
- (a)(i) Risk assessments should include at a minimum data gathering, storage and transmission through information systems.

Demonstrating Compliance: Desktop Review

- (a) Information system document(s) describing the organization's risk assessment processes.
- (a) Evidence of periodic risk assessment(s) conducted, including any applicable corrective actions based on findings.

Demonstrating Compliance: Validation Review

- (a) Interview with responsible individuals (i.e., IT, compliance, risk manager).

Standard RM 4: Business Continuity

The organization maintains a business continuity plan designed to promote continuity of care during unplanned events.

RM 4-1: Business Continuity Plan

The organization:

a. Maintains a business continuity plan, which: [4]
    i. Is developed by an inter-departmental team and approved by leadership
    ii. Outlines the systems and processes that must be maintained
    iii. Describes how business continuity is maintained given various scenarios
b. Requires the business continuity plan to be used or tested at least every 2 years and incorporates corrective actions and updates in response to any findings [4]

Interpretive Information

- The business continuity plan must address all employees, including telecommuters, as applicable.
- (a)(iii) Emergency scenarios may include (but are not limited to): technology or communication failures, incidents involving data loss or corruption, natural disasters, pandemics, etc.
- (a)(iii) Scenarios may impact the length of time information systems are not functioning or accessible.
- (b) URAC will accept documentation of an actual disruption to business operations or a test of its business continuity plan, including tabletop test.

Demonstrating Compliance: Desktop Review

- (a)-(b) Business continuity plan document(s) describing the organization business continuity processes.
- (b) Evidence of business continuity plan usage or testing, including any corrective actions taken in response to findings.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

Focus Area: Operations and Infrastructure (OPIN)

Standard OPIN 1: Business Management

The organization reviews and disseminates policies and processes in a timely manner. Delegation arrangements are maintained.

OPIN 1-1: Policy and Process Maintenance

The organization:

a. Maintains policies and processes that include: [4]
    i. A record of effective dates, review dates, revision dates and identification of approval authority
    ii. Review of policies and processes at least every 36 months
    iii. Dissemination of new, changed and/or updated policies and processes to staff in a timely manner

Interpretive Information

- (a)(ii) URAC will require organizations to review policies and processes no less than every 36 months.
- (a)(iii) "Timely manner" is determined by the organization.

Demonstrating Compliance: Desktop Review

- (a) Policy and process maintenance document(s) describing how the organization maintains, reviews and disseminates policies and processes.
- (a)(i) Evidence of recording review dates, revision dates, effective dates and approval authority.
- (a)(ii) Evidence of policy and process review at least every 36 months.

Demonstrating Compliance: Validation Review

- (a)(iii) Interview with staff.

OPIN 1-2: Delegation Management

The organization retains accountability for delegated functions under the scope of the accreditation by:

a. Maintaining executed agreements with delegated entities [8]

b. Conducting annual oversight of the quality of performance and ongoing compliance with pertinent standards [4]

Interpretive Information

- These elements of performance apply to standards within the scope of this accreditation performed by contractors; they do not apply to individuals.
- When a contractor is recognized by URAC for the standard(s) it performs on behalf of the organization:
  - In lieu of an oversight plan, the organization conducts validation of the contractor's accreditation or certification status. Proof of the contractor's URAC recognition will demonstrate compliance with this element of performance and standards/elements of performance applicable to delegated functions.
- When a contractor is not recognized by URAC for the standard(s) it performs on behalf of the organization, a contractor performance oversight plan is adopted:
  - Oversight of compliance with URAC standards may not be assigned to the contractor by the organization.
  - Oversight results are evidence that the organization is actively managing the contractor's compliance with URAC standards for delegated functions.

Demonstrating Compliance: Desktop Review

- (a)-(b) Delegation Plan Document(s) describing the oversight of delegated functions.
  - For contractors that are not URAC-accredited or -certified for the delegated standard(s), annual oversight should use the demonstrating compliance methods in this program guide.
  - For contractors that are URAC-accredited or -certified for the delegated standard(s), annual oversight should include verification of continuous accreditation or certification.
- (a) List of delegated functions to include the URAC standard(s) that apply to each function.
- If the organization does not delegate under the scope of the accreditation, submit an attestation to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a) The delegation agreement (redacted as needed), including documentation of the functions that are delegated.
- (b) If the contractor is URAC-accredited or -certified for the standard(s) delegated, proof of the accreditation or certification.
- (b) For contractors that are not URAC-accredited or -certified for the standards delegated, evidence of annual oversight using demonstrating compliance methods in this program guide.

Standard OPIN 2: Staff Management

Staff are appropriately licensed and screened prior to hire. Licensure and/or certifications are verified no less than every three years. Staff members are trained initially and on an ongoing basis.

OPIN 2-1: Clinical Staff Credentialing

The organization:

a. Primary source verifies the current licensure and/or certification of staff whose job description requires licensure and/or certification: [8]

   i. Prior to hire

   ii. No less than every three (3) years

b. Requires staff to notify the organization in a timely manner of an adverse change in licensure and/or certification status and implements corrective action in response to adverse change(s) [8]

Interpretive Information

- (a) Primary source verification is obtained directly from the licensing or certification source and should include current license information for the individual, the date verified and, if verified in writing or by telephone, the individual verifying the license.
- (a)(ii) If the organization's policy requires re-verification more frequently than URAC, URAC Reviewers will seek compliance with the organization's stated policy during the validation review.
- (a) Even when full accreditation or certification is achieved, if this standard is identified as "Not Met," a follow-up validation review will occur within six (6) months to verify full compliance.
- (b) "Timely manner" is determined by the organization.

Demonstrating Compliance: Desktop Review

- (a) Credentialing document(s) outlining how the organization primary source verifies licenses and/or certifications.
- (b) Credentialing document(s) outlining the organization's requirement for staff reporting adverse change in licensure and/or certification and corrective actions taken in response to adverse changes.

Demonstrating Compliance: Validation Review

- (a) Random sample of personnel files to review primary source verification of licenses and/or certifications.

OPIN 2-2: Employment Screening

The organization's Employee Screening Program receives results prior to hire and responds appropriately to:

a. A background check on employees who handle personal information [8]

b. A drug test/screen for employees who have access to pharmaceuticals [8]

c. A drug test/screen for all employees [L]

Interpretive Information

- (a)-(c) Findings directly from the entity performing the background check and/or drug screen should be readily available. The results may be redacted.
- (a) The background check may include review of identification records, criminal records, sex offender status and other applicable information.
- (b) Drug testing/screening is not limited to illicit drugs.

Demonstrating Compliance: Desktop Review

- (a) Employee screening program document(s) outlining the organization's background check process.
- (b)-(c) Employee screening program document(s) outlining the organization's drug test/screen process.
- (b) If the organization does not have access to pharmaceuticals, submit a statement to that effect so this standard may be identified as not applicable.
- (c) If the organization chooses not to meet this leading indicator, submit an attestation to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a)-(c) Random sample of personnel files to verify background checks and drug screens are completed prior to hire as appropriate.

OPIN 2-3: Staff Training Programs

The organization:

a. Educates staff on their responsibilities regarding privacy and security of patient information [8]

b. Provides training to staff, to include: [4]

   i. Initial orientation and/or job-related training for all staff before assuming assigned roles and responsibilities

   ii. Ongoing training to maintain current job knowledge

Interpretive Information

- (b)(ii) Organizations determine the frequency and topics for training, which may depend on criteria such as changes in laws and regulations, changes in standards and shifts in business functions or strategy.

Demonstrating Compliance: Desktop Review

- (a)-(b) Training program document(s) outlining training topics, frequency of training on each topic and the method(s) for tracking individual participation.
- (a)-(b) Example training materials.

Demonstrating Compliance: Validation Review

- (a)-(b) Random sample of personnel files to verify the implementation of staff training programs.

OPIN 2-4: Code of Ethical Conduct

The organization:

a. Maintains a code of ethical conduct, which includes: [4]
    i. Ethical principles
    ii. Reporting mechanisms for unethical conduct
    iii. Actions taken when unethical conduct is identified
b. Implements mechanism(s) for confirming employee understanding [4]

Interpretive Information

- (a)(i) Ethical principles should include both business related ethics as well as health care ethics as appropriate.
- (a)(i) The organization's code of ethical conduct outlines ethical principles relevant to their business, which may include conflict of interest, false claims, fraud, waste and abuse, illegal activities, whistleblower situations, avoidance of discrimination, reporting impaired practices, professional use of digital media, etc.

Demonstrating Compliance: Desktop Review

- (a)-(b) Code of ethical conduct demonstrating compliance with this element of performance.

Demonstrating Compliance: Validation Review

- (b) Random sample of personnel files to verify staff confirmed their understanding of the code of conduct.

OPIN 2-5: Employee Diversity, Equity and Inclusion

The organization:

a. Promotes employee: [4]
    i. Diversity
    ii. Equity
    iii. Inclusion

Interpretive Information

- (a) The organization demonstrates its commitment to diversity, equity and inclusion through one or more of the following: policies and procedures, EEO statements in job description recruitment advertisements stating organizational commitment to fair hiring practices in regard to age, gender, disability, sexual orientation, ethnicity, race, language, background and experience, etc.
- (a)(i) Diversity promotes a balanced representation of staff.
- (a)(ii) Equity ensures opportunities for all staff.
- (a)(iii) Inclusion fosters a sense of belonging among staff.

Demonstrating Compliance: Desktop Review

- (a) Employee diversity, equity and inclusion includes one or more of the following: policies, procedures and EEO statements outlining how the organization promotes diversity, equity and inclusion.

Demonstrating Compliance: Validation Review

- (a) Interview with leadership to demonstrate knowledge of policies, procedures and implementation of identified tactics.

Standard OPIN 3: Clinical Leadership

A senior clinical staff person oversees the services provided.

OPIN 3-1: Clinical Staff Leadership

The organization:

a. Designates at least one senior clinical staff person who is: [8]

   i. Currently licensed or otherwise permitted to practice a health profession in the relevant jurisdiction(s)

   ii. Qualified to perform clinical oversight for the services provided

   iii. Responsible for oversight of clinical decision-making aspects of the program and provides clinical guidance

Interpretive Information

- Senior clinical staff has licensure, certification, and qualifications representative of the program being offered.
- (a)(i) An individual may practice a health profession without a license when allowed by the relevant jurisdiction. The individual is required to follow relevant jurisdictional requirements to practice that health profession.
- (a)(i) The senior clinical staff person is responsible for maintaining licensure in compliance with laws and regulations in any jurisdiction where compliance is required to do business (i.e., the relevant jurisdiction(s)).

Demonstrating Compliance: Desktop Review

- (a) Job description or scope of work for the senior clinical staff person.
- (a)(i)-(a)(ii) Evidence of the senior clinical staff person meeting the requirements in the job description.

Demonstrating Compliance: Validation Review

- (a) Review the senior clinical staff person's credentials to verify licensure and qualifications.
- (a)(iii) Interview with leadership.

Focus Area: Performance Monitoring and Improvement (PMI)

Standard PMI 1: Quality Management Scope

The organization maintains a quality management program that promotes measurement and implementation of quality improvement activities based on the performance results. The quality management program is overseen by a quality oversight body. [M]

PMI 1-1: Quality Structure

The organization's quality management program:

a. Identifies metrics and the quantifiable goals relevant to the program

b. Maintains a quality oversight body responsible for monitoring metrics and progress in meeting quantifiable goals and overseeing improvement activities

Interpretive Information

- (a) Metrics and quantifiable goals are defined by the organization based on business functions.
- (a) Quantifiable goals may be goals set by the organization, internally, or those set by the industry, externally.

Demonstrating Compliance: Desktop Review

- (a)-(b) Quality Program Document(s) describing the organization's quality management processes.
- (a) Evidence of metrics and quantifiable goals.

Demonstrating Compliance: Validation Review

- (a)-(b) Interview with quality staff.
- (b) Evidence of quality oversight body monitoring metrics and progress in meeting quantifiable goals and overseeing improvement activities (i.e., meeting minutes).

Standard PMI 2: Quality Data Collection and Evaluation

The organization maintains a quality management program that promotes accurate collection, analysis and evaluation of data.

PMI 2-1: Data Collection and Evaluation

The organization's quality management program:

a. Collects accurate data for each metric [8]

b. Monitors progress in meeting each quantifiable goal [8]

c. Analyzes data and identifies performance trends for each metric at a minimum annually [8]

d. Designs and implements activities to improve performance levels when the need is indicated through monitoring and analysis [8]

Interpretive Information

- (c) Organizations should identify baseline, past and current performance to analyze trends.
- (d) Improvement activities should, at a minimum, outline the expected metric, the strategies to get to that metric, defined regular measurement and reporting, evaluation of the effectiveness of the strategy and revision for strategies that do not meet intended results.

Demonstrating Compliance: Desktop Review

- (a)-(d) Quality Program Document(s) describing the organization's quality management processes.
- (d) Evidence of activities implemented, if applicable.

Demonstrating Compliance: Validation Review

- (a)-(d) Interview with quality staff.
- (b)-(c) Evidence of monitoring performance progress and analyzing data and performance trends (i.e., meeting minutes).
- (d) Evidence of activities implemented in response to metrics not meeting quantifiable goals.

Focus Area: Consumer Protection and Empowerment (CPE)

Standard CPE 1: Protection of Consumer Information

The organization ensures the privacy and security of consumer information.

CPE 1-1: Privacy and Security of Consumer Information

The organization:

a. Executes business associate agreements with business associates as required by applicable jurisdictional laws and regulations [8]

b. Addresses situations where an individual or entity's functions or services do not involve the use or disclosure of confidential/protected health information or individually identifiable health information, but their work puts them in the vicinity of this type of information [8]

c. Detects, contains and corrects privacy and security violations and data breaches [8]

Interpretive Information

- (a) If applicable jurisdictional laws and regulations do not require business associate agreements, demonstration of this law or regulation is required.
- (b) Examples of individuals or entities that may be in the vicinity of confidential information include (but are not limited to): janitorial staff, installation/repair technicians, financial auditors, etc.

Demonstrating Compliance: Desktop Review

- (a) Sample or template business associate agreements.
- (b) Privacy and security document(s) defining the types of individuals affected and the methods used to protect confidentiality.
- (c) Privacy and security document(s) outlining how the organization detects, contains and corrects privacy and security violations and data breaches.

Demonstrating Compliance: Validation Review

- (a) Executed business associate agreements.

CPE 1-2: Internal Safeguards

The organization:

a. Promotes internal privacy and security safeguards to include: [8]
    i. Who within the organization has access to confidential/protected health information or individually identifiable health information
    ii. Confirmation of responsibility for individuals within the organization who have access to confidential/protected health information or individually identifiable health information to maintain confidentiality

Interpretive Information

- (a)(ii) Organizations may use an electronic system to document employee confirmation of their responsibility.

Demonstrating Compliance: Desktop Review

- (a) Privacy and security document(s) outlining the organization's safeguards to protect consumer privacy and security.

Demonstrating Compliance: Validation Review

- (a)(ii) Random sample of personnel files to verify staff understands their responsibility to maintain confidentiality.

Standard CPE 2: Consumer Safeguards and Communication

The organization has mechanisms to keep consumers safe and informed. There are mechanisms for consumers to communicate their issues and concerns with services to the organization.

CPE 2-1: Consumer Diversity, Equity and Inclusion

The organization:

a. Promotes consumer: [4]
    i. Diversity
    ii. Equity
    iii. Inclusion

Interpretive Information

- (a) The organization demonstrates its commitment to diversity, equity and inclusion through one or more of the following: policies and procedures and/or organizational statements demonstrating an appreciation for cultural competence in their consumer interface based on the culture, race and ethnicity of the populations that they serve.
- (a)(i) Diversity promotes an appreciation for the traditions and beliefs of diverse patient populations and an understanding of what effect stereotyping can have on decision making involving their consumer population.
- (a)(ii) Equity ensures understanding of cross-cultural awareness for problem solving and promoting consumer compliance.
- (a)(iii) Inclusion involves an understanding of techniques to deal with language or communication barriers.

Demonstrating Compliance: Desktop Review

- (a) Consumer diversity, equity and inclusion document(s) outlining how the organization educates regarding diversity, equity and inclusion in their consumer population.

Demonstrating Compliance: Validation Review

- (a) Interview with leadership.

CPE 2-2: Consumer Safety Protocols

The organization maintains consumer safety protocols to:

a. Respond, on an urgent basis, to situations that pose an immediate threat to the health and safety of consumers [8]

Interpretive Information

- (a) The organization must have at least one protocol to respond, on an urgent basis, to reports of immediate threats to consumer safety.
- (a) Examples of immediate threats to consumer safety may include suicide threats, abuse, medical emergencies, etc.

Demonstrating Compliance: Desktop Review

- (a) Consumer safety document(s) to address immediate consumer safety threats.

Demonstrating Compliance: Validation Review

- (a) Interview with staff.

CPE 2-3: Consumer Complaint Process

The organization's consumer complaints process includes:

a. A process to respond to and resolve complaints for the consumer in a timely manner [8]

b. Reporting analysis of consumer complaints to the quality oversight body [4]

Interpretive Information

- (a) Consumers, or another person acting on behalf of the consumer, may submit a complaint.
- (b) Analysis of complaint data does not include discussion of individual complaints. Analysis of complaint data may include turnaround time, complaint volume, complaint type, etc.
- (b) See PMI 1-1 regarding quality oversight body responsibilities.

Demonstrating Compliance: Desktop Review

- (a) Consumer complaint document(s) describing the complaint process.
- (b) Quality Program or Complaint Document(s) describing the organization's process for complaint reporting to the quality oversight body

Demonstrating Compliance: Validation Review

- (a) Review of consumer complaint documentation to verify complaint resolution timeframes are met.
- (b) Evidence of complaint analysis reported to the quality oversight body (i.e., meeting minutes).

CPE 2-4: Health Literacy Promotion

The organization's health communication practices:

a. Require consumer materials to be in plain language [8]

b. Provide information and guidance on health literacy to staff who write or review content for consumers [4]

Interpretive Information

- (a) Plain language resources are widely available. The organization should identify which resource they intend to use and document it's use.

Demonstrating Compliance: Desktop Review

- (a) Health literacy document(s) outlining the plain language resources used and how use of the resource is documented.
- (a) Evidence of mechanism used to document health communications use plain language.
- (b) Health literacy document(s) outlining how information and guidance is provided to staff.
- (b) Evidence of information and guidance provided to staff.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

CPE 2-5: Consumer Marketing and Communication Safeguards

The organization:

a. Implements consumer marketing and communication practices, which include: [4]
    i. Mechanisms that safeguard against misrepresentations about the organization's services
    ii. Prompt response to detected problems and corrective action as needed

Interpretive Information

- (a) Marketing and communication practices may include written/print materials, online/digital materials, web site, newsletters, press releases, social media, brochures, etc.
- (a)(i) Examples of mechanisms to safeguard against misrepresentation may include inter-departmental review, review checklists, etc.
- (a)(ii) "Prompt" is defined by the organization.

Demonstrating Compliance: Desktop Review

- (a) Marketing and communication document(s) describing the organization's marketing and communication processes.
- (a) Example evidence of marketing and communication material development and/or review.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

FOCUS AREA: Pharmacy Operations

STANDARD P-OPS 1: Scope of Services

The pharmacy's scope of services is clearly outlined.

P-OPS 1-1: Services

The pharmacy:

a. Defines the following: [2]
    i. Geographic location(s) served
    ii. Services provided
b. Facilitates an alternative source of medication(s) for patients when the pharmacy has limited access and/or availability [8]
c. Promotes cost effective health care practices [4]

Interpretive Information

- (b) Scenarios where the pharmacy has limited access or availability to a medication may include Limited Distribution Drugs, out of network, backorder, etc.
- (c) Cost effective health care practices help decrease the cost burden to the health care system.
- (c) Examples of cost-effective health care practices include generic substitution, decreasing polypharmacy, etc.

Demonstrating Compliance: Desktop Review

- (a) Document(s) defining the geographic locations served and the services provided.
- (b) Document(s) outlining how the pharmacy facilitates alternative sources of medications.
- (c) Document(s) outlining how the pharmacy promotes cost-effective health care practices.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

STANDARD P-OPS 2: Prescription Processing and Dispensing

Prescription processing and dispensing promotes patient safety.

P-OPS 2-1: Reviewing Patient Information

The pharmacy:

a. Obtains, maintains and documents: [8]
    i. Patient health history
    ii. Medication history
    iii. Allergies and past sensitivities
    iv. Information necessary to consult with the prescriber and counsel the patient and caregivers

Interpretive Information

- (a)(ii) Medication history for the patient includes any previous therapies related to the prescribed medication(s) the pharmacy is dispensing.
- (a)(iv) Information necessary to consult with the prescriber and counsel the patient may include social determinants of health, lab values, adherence history, etc.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy obtains, maintains and documents patient information.

Demonstrating Compliance: Validation Review

- (a) Observation of how the pharmacy documents patient information.

P-OPS 2-2: Verifying Eligibility

The pharmacy:

a. Verifies: [2]
    i. That a patient is within the scope of pharmacy services
    ii. Patient coverage benefits
    iii. Eligibility for financial assistance, if needed

Interpretive Information

- (a)(i) Scope of services verification may include the patient's disease state, prescribed medication, counseling required, etc.
- (a)(iii) Not all patients will require financial assistance. If the patient does require financial assistance, the organization has a process to verify what financial assistance is available to that patient for the medication prescribed.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for verifying patient eligibility.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

P-OPS 2-3: Resolving Issues

The pharmacy:

a. Communicates in a timely manner with the patient, prescriber and/or payer to resolve issues related to: [4]
    i. Drug utilization review
    ii. Coverage or benefits
    iii. Out of stock and backorder products

Interpretive Information

- (a) "Timely manner" is determined by the organization.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for communicating with the patient, prescriber, and/or payer to resolve issues.

Demonstrating Compliance: Validation Review

- (a) Interview with staff.

P-OPS 2-4: Dispensing Practices

The pharmacy:

a. Prevents contamination in the dispensing process [4]

b. Documents lot numbers of products dispensed for tracking purposes [L]

Interpretive Information

- (a) Examples of preventing contamination may include cleaning processes for dispensing materials, use of separate bins for each patient, use of separate dispensing materials for hazardous medication, chemotherapy, or antibiotics, etc.
- (b) Through lot number documentation on dispensed products, pharmacies can track patients who have received a recalled medication.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy prevents contamination.
- (b) Document(s) outlining how the pharmacy documents lot numbers.
  - If the organization chooses not to meet this leading indicator, submit a statement to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a) Observation of how the pharmacy prevents contamination.
- (b) Observation of how the pharmacy documents lot numbers [optional].

P-OPS 2-5: Machine and Equipment Maintenance

The pharmacy:

a. Maintains machines and equipment used for dispensing in accordance with manufacturer guidelines and state and federal regulations including documented cleaning, calibration, and auditing [4]

Interpretive Information

- (a) Examples of machines or equipment include tablet counters, automated dispensing machines, unit dose packagers, compounding equipment, etc. This does not apply to refrigerators, freezers, or label printers.
- (a) If processes supporting maintenance of machines and equipment are located within the manufacturer manual, it is appropriate to reference the manual and outline how staff access the manual.
- (a) If a manufacturer or third-party vendor performs maintenance, retain the maintenance records.

Demonstrating Compliance: Desktop Review

- (a) List of machines and equipment used in the dispensing process.
- (a) Document(s) describing the pharmacy's process for maintaining machines and equipment in accordance with manufacturer guidelines and state and federal regulations.
- (a) Sample documentation or template demonstrating documentation of cleaning, calibration, and auditing of a machine or equipment.
- (a) If the pharmacy does not use machines or equipment within the scope of this accreditation, submit an attestation to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a) Evidence demonstrating documentation of cleaning, calibration, and auditing for each machine and equipment used within the dispensing process.

STANDARD P-OPS 3: Dispensing Accuracy Monitoring and Promotion

The pharmacy monitors and promotes dispensing accuracy.

P-OPS 3-1: Dispensing Accuracy

The pharmacy:

a. Monitors dispensing accuracy through: [8]
    i. Tracking both errors and near misses
    ii. Reporting errors to appropriate internal and external entities
    iii. Analyzing data and identifying performance trends on dispensing accuracy for review by the quality oversight body at least quarterly
    iv. Implementing action plans designed to improve or correct identified problems as needed

b. Reviews relevant external literature at least annually, to incorporate safety and error prevention recommendations into pharmacy practice as appropriate [4]

c. Utilizes proactive risk assessments [4]

d. Shares safety and error prevention recommendations and updates with staff [4]

Interpretive Information

- (a) The URAC dispensing accuracy measure includes tracking of wrong drug, wrong patient, wrong strength, wrong dosage form, wrong instructions, and wrong quantity.
- (a)(i) Near misses may be identified as an error that is caught prior to leaving the pharmacy.
- (a)(iii) Analysis and performance trending requires identification of quantifiable goals and monitoring progress in meeting these goals.
- (a)(iii) Analysis and performance trending for dispensing accuracy should include both errors and near misses.
- (b) Sources of relevant external literature may include the Institute for Safe Medication Practices (ISMP), the Institute of Medicine (IOM), the United States Pharmacopeia (USP), etc.
- (c) The Failure Mode and Effects Analysis (FMEA) may be used to identify areas of potential risk and gauge impact before an error takes place.
- (d) Safety and error prevention recommendations may come from error monitoring, reviews of safety literature, and/or proactive risk assessments.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy monitors dispensing accuracy, including tracking, reporting, analyzing, trending, and implementing action plans.
- (a) Sample documentation or template demonstrating quality oversight body review of dispensing accuracy analysis and trending.
- (b) Document(s) outlining how the pharmacy reviews and incorporates relevant literature recommendations.
- (b) Sample documentation demonstrating a literature review, including any recommendations for incorporation into pharmacy practice.
- (c) Document(s) outlining how the pharmacy utilizes proactive risk assessments.
- (c) Sample documentation demonstrating a completed proactive risk assessment.
- (d) Document(s) outlining how the pharmacy shares safety and error prevention recommendations with staff.
- (d) Sample documentation demonstrating a safety or error prevention recommendation shared with staff.

Demonstrating Compliance: Validation Review

- (a) Evidence demonstrating quality oversight body review of dispensing accuracy analysis and trending at least quarterly.
- (a) Evidence demonstrating any action plans designed to improve or correct identified problems.
- (b) Evidence demonstrating literature reviewed at least annually, including any recommendations for incorporation into pharmacy practice.
- (c) Evidence demonstrating completed proactive risk assessments.
- (d) Interview with staff.

STANDARD P-OPS 4: Adherence Monitoring

The pharmacy monitors and promotes medication adherence.

P-OPS 4-1: Adherence

The pharmacy:

a. Monitors medication adherence to identify when a patient is non-adherent [4]

b. Promotes medication adherence when a patient is identified as non-adherent [4]

c. Analyzes data and identifies performance trends on adherence for review by the quality oversight body at least once in a calendar year [4]

Interpretive Information

- (c) Analysis and performance trending requires identification of quantifiable goals and monitoring progress in meeting these goals.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy monitors medication adherence to identify when a patient is non-adherent.
- (b) Document(s) outlining how the pharmacy promotes medication adherence when a patient is identified as non-adherent.
- (c) Document(s) outlining how the pharmacy analyzes and identifies adherence performance trends for review by the quality oversight body.
- (c) Sample documentation or template demonstrating quality oversight body review of adherence analysis and trending.

Demonstrating Compliance: Validation Review

- (a)-(b) Interview with staff.
- (c) Evidence demonstrating quality oversight body review of adherence analysis and trending at least once in a calendar year.

STANDARD P-OPS 5: Product Management

Inventory is managed to promote employee and patient safety.

P-OPS 5-1: Inventory Temperature Management

The pharmacy:

a. Continuously monitors all drug storage areas to maintain defined ranges for: [4]
    i. Refrigerator temperature
    ii. Freezer temperature
    iii. Ambient room air temperature
    iv. Humidity
b. Determines acceptable excursions in temperature and humidity for drug storage areas in accordance with manufacturer guidelines or other published literature [4]
c. Handles breakdowns resulting in excursions that exceed guidelines from the manufacturer or published literature [4]
d. Conducts inventory storage thermal mapping [L]

Interpretive Information

- (a) Continuous monitoring requires electronic monitoring.
- (a) Temperature and humidity ranges are defined by the organization.
- (a)(ii) Freezer temperatures are required to be continuously monitored when storing medications.
- (b) Manufacturer guideline information may be published or provided ad hoc from the manufacturer directly.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for continuous monitoring of drug storage areas, including the defined temperature and humidity ranges.
- (a) If the pharmacy does not store medications within one of these drug storage areas within the scope of this accreditation, submit an attestation to that effect so this sub-element may be identified as not applicable.
- (b) Document(s) outlining how the pharmacy determines acceptable excursions.
- (c) Document(s) outlining how the pharmacy handles breakdowns resulting in excursions that exceed manufacturer guidelines or published literature.
- (d) Document(s) describing the pharmacy's process for conducting inventory storage thermal mapping.
    - If the organization chooses not to meet this leading indicator, submit a statement to that effect so this standard may be identified as not applicable.
- (d) Sample documentation demonstrating a thermal map completed for a drug storage area [optional].

Demonstrating Compliance: Validation Review

- (a) Evidence demonstrating continuous monitoring for all drug storage areas.
- (d) Evidence demonstrating thermal maps completed for drug storage areas [optional].

P-OPS 5-2: Hazardous Material Management

The pharmacy:

a. Identifies the hazardous materials and medications kept in the pharmacy [4]

b. Handles, stores and disposes of hazardous materials and medications in accordance with USP 800 guidelines [8]

c. Makes readily available and educates employees on the use of [8]

   i. Safety Data Sheets (SDS)

   ii. Spill kits

   iii. Eye wash stations

Interpretive Information

- (a) This element is applicable to all organizations.
- (a) The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other hazardous drugs used in healthcare settings, as well as provides criteria to identify hazardous drugs not on the list.
- (b) Hazardous materials and medications should be managed in compliance with USP 800 guidelines. See these guidelines for additional information on maintaining a list of hazardous drugs and conducting risk assessments.
- (b) Organizations should perform an assessment of risk to determine and implement alternative containment strategies when the application of all USP 800 requirements are not necessary or feasible for a particular hazardous drug.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy identifies hazardous materials and medications.
- (a) List of hazardous materials and medications kept in the pharmacy
- (b) Document(s) outlining how the pharmacy handles, stores, and disposes of hazardous materials in compliance with USP 800 requirements.
- (b) List of risk assessments completed to store hazardous materials and medications outside of USP 800 requirements.
- (b) Sample documentation demonstrating a completed hazardous medication risk assessment.
- (c) Document(s) requiring safety data sheets (SDS), employee spill kits, and eye wash stations in the pharmacy and how the organization educates on the use of these items.
- (b)-(c) If the pharmacy does not keep any hazardous materials and medications in the pharmacy within the scope of this accreditation, submit an attestation to that effect so these elements may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (b) Observation of how the pharmacy handles, stores, and disposes of hazardous materials and medications.
- (c) Observation of how the pharmacy makes Safety Data Sheets (SDS), employee spill kits, and eye wash stations readily available within the pharmacy.

P-OPS 5-3: Manufacturer and FDA Requirements

The pharmacy:

a. Identifies and implements Food and Drug Administration (FDA) guidance and self-imposed manufacturer requirements, and promotes ongoing compliance [4]

b. Notifies patients and prescribers of a new FDA guidance or self-imposed manufacturer restriction that could cause a potential safety event [4]

Interpretive Information

- (b) Potential safety events may include new black box warnings, new Risk Evaluation and Mitigation Strategies (REMS) programs, additional adverse drug events added by the manufacturer, etc.
- (b) New FDA guidance or manufacturer requirements may derive from pharmacovigilance activities performed by pharmacies, such as aftermarket adverse drug event reporting.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy identifies and implements FDA guidance and manufacturer requirements, and how ongoing compliance is promoted.
- (b) Document(s) describing the pharmacy's process for notifying patients and prescribers of a new FDA guidance or manufacturer restriction, including when notification occurs.

Demonstrating Compliance: Validation Review

- (a)-(b) Interview with staff.

FOCUS AREA: Medication Distribution

STANDARD P-MD 1: Distribution Management

Distribution criteria are established and tested prior to shipping medications. Packing and shipping processes are audited to monitor for compliance.

P-MD 1-1: Defining Distribution Criteria

The pharmacy:

a. Defines evidence-based distribution criteria, including temperature range(s), packing product(s) and shipping duration(s), for the following types of medications: [4]

   i. Refrigerated

   ii. Frozen

   iii. Controlled room temperature

Interpretive Information

- (a) Evidence based criteria references may include USP 695, World Health Organization, manufacturer guidelines, etc.
- (a) Temperature ranges, including excursions, should be defined through evidence.
- (a)(iii) The organization uses evidence-based criteria to determine which room temperature medications are shipped under controlled room temperature.

Demonstrating Compliance: Desktop Review

- (a) Document(s) defining the distribution criteria for each medication type, including references used to determine criteria.
- (a) If the pharmacy does not ship a medication type within the scope of this accreditation, submit an attestation to that effect so this sub-element may be identified as not applicable.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

P-MD 1-2: Qualification Testing

The pharmacy:

a. Develops and initiates a qualification testing plan to validate distribution criteria is met: [8]

    i. Before utilization or modification of each packing and shipping procedure

    ii. For each temperature profile where medications are shipped

    iii. Using multiple shipments for each packing and shipping procedure

    iv. Using continuous monitoring devices

Interpretive Information

- (a) True ship test(s) are used to adequately qualify the package for pharmacy use. Chamber testing can inform the qualification testing plan but does not alone meet the intent of this element.
- (a) The pharmacy is responsible for ensuring proper qualification testing is conducted, but they may use outside vendors to help design and implement those tests.
- (a) Qualification testing documentation may include package type/size, pack-out, date shipped, time in distribution, temperature results throughout shipment, location shipped to, delivery method, etc.
- (a)(i) Modification occurs when the shipping container or types and/or amounts of packing materials (e.g., bubble wrap, packing paper, ice packs, etc.) changes. This does not include a change in manufacturer of packing materials where the type and/or amount of material does not change.
- (a)(ii) Testing for each temperature profile where medications are shipped should represent the extreme temperatures experienced.
- (a)(iii) “Multiple” is defined by the organization.
- (a)(iii) Multiple passing ship tests for each packing and shipping procedure will determine consistency and accuracy of the packing and shipping procedures used to meet the distribution criteria.
- (a) Even when full accreditation or certification is achieved, if this standard is identified as “Not Met,” a follow-up validation review will occur within six (6) months to verify full compliance.

Demonstrating Compliance: Desktop Review

- (a) Qualification testing plan outlining how the pharmacy plans to validate the distribution criteria is met for each medication type through testing.
- (a) Sample documentation demonstrating a qualification test completed following the qualification testing plan.
- (a) If the pharmacy has completed all qualification testing prior to this accreditation application, submit an attestation to that effect.

Demonstrating Compliance: Validation Review

- (a) Guided review of completed qualification testing.

P-MD 1-3: Packing and Shipping Procedures

The pharmacy:

a. Designs and implements packing and shipping procedures based on the distribution criteria and qualification testing results for each medication type [4]

b. Provides training to appropriate staff on packing and shipping procedures [4]

Interpretive Information

- (a) Packing and shipping procedures include the pack-out procedures used.
- (a) Distribution criteria includes temperature profile, packing materials, and shipping duration.
- (a) Medication types include refrigerated, frozen, and controlled room temperature.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy designs and implements packing and shipping procedures.
- (b) Document(s) describing the pharmacy's process for training staff on packing and shipping procedures.
- (b) Sample documentation demonstrating training material used to provide training on packing and shipping procedures.

Demonstrating Compliance: Validation Review

- (a) Guided review of completed packing and shipping procedures for each medication type.
- (b) Interview with packing and shipping staff.

P-MD 1-4: Distribution Auditing

At least annually, the pharmacy:

a. Audits each packing and shipping procedure [8]

b. Reviews, and updates as needed, packing and shipping procedures based on: [4]

   i. Distribution auditing results

   ii. Shipping complaints

Interpretive Information

- (a) Example of audits may include periodic ongoing testing, audits of staff completed pack-outs, audits on pack-out weights for consistency, etc.
- (a) Even when full accreditation or certification is achieved, if this standard is identified as "Not Met," a follow-up validation review will occur within six (6) months to verify full compliance.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy audits each packing and shipping procedure at least annually.
- (a) Sample documentation demonstrating a completed audit.
- (a) If the pharmacy has not completed all qualification testing prior to this accreditation application and is therefore not in the auditing phase, submit an attestation to that effect.
- (b) Document(s) describing the pharmacy's process for reviewing and updating packing and shipping procedures based on distribution auditing results and shipping complaints.
- (b) Sample documentation or template demonstrating review of packing and shipping procedures based on distribution audit results and shipping complaints.

Demonstrating Compliance: Validation Review

- (a) Guided review of completed audits on packing and shipping procedures.
- (b) Evidence demonstrating annual review of packing and shipping procedures, and updates as needed, based on distribution auditing results and shipping complaints.

STANDARD P-MD 2: Shipping Logistics

The pharmacy holds shipments when needed, tracks packages after they leave the pharmacy, and handles breakdowns in the shipping process.

P-MD 2-1: Holding Shipments

The pharmacy:

a. Monitors for weather and other expected delays [2]

b. Develops criteria to determine when a shipment should be held [2]

Interpretive Information

- Intentionally left blank.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy monitors for weather and other expected delays.
- (b) Document(s) defining the criteria for when shipments should be held.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

P-MD 2-2: Tracking Shipments

The pharmacy:

a. Traces a package after it leaves the facility [2]

b. Notifies the patient and/or prescriber if shipments will be delayed [4]

Interpretive Information

- Intentionally left blank.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy traces a package after it leaves the facility.
- (b) Document(s) describing the pharmacy's process for notifying patients and/or prescribers of shipment delays, including when notification occurs.

Demonstrating Compliance: Validation Review

- (a)-(b) Interview with staff.

P-MD 2-3: Handling Breakdowns

The pharmacy:

a. Determines the excursion allowances of a product in accordance with manufacturer guidelines or published literature [4]

b. Advises and instructs the patient and/or prescriber regarding the stability of a product when there is a breakdown in the shipping process [4]

Interpretive Information

- (a) Excursion allowances include deviations outside the manufacturer guidelines or other published literature recommended temperature range.
- (a) Manufacturer guideline information may be published or provided ad hoc from the manufacturer directly.
- (b) Instructions to the patient and provider may include disposal methods, send back procedures, possible missed doses, etc.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy determines excursion allowances.
- (b) Document(s) describing the pharmacy's process for advising and instructing patients and/or providers when there is a breakdown in the shipping process.

Demonstrating Compliance: Validation Review

- (b) Interview with staff.

STANDARD P-MD 3: Distribution Accuracy Monitoring

The pharmacy monitors distribution accuracy, analyzes aggregate data, identifies performance trends, and implements corrective actions when needed.

P-MD 3-1: Distribution Accuracy

The pharmacy:

a. Monitors distribution accuracy through: [8]
    i. Tracking distribution errors
    ii. Reporting distribution errors to appropriate internal and external entities
    iii. Analyzing data and identifying performance trends on distribution accuracy for review by the quality oversight body at least quarterly
    iv. Implementing action plans designed to improve or correct identified problems as needed

Interpretive Information

- (a) The URAC distribution accuracy measure includes mailed with incorrect address, and mailed with correct address, but delivered to the wrong address.
- (a)(iii) Analysis and performance trending requires identification of quantifiable goals and monitoring progress in meeting these goals.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy monitors distribution accuracy, including tracking, reporting, analyzing, trending, and implementing action plans.
- (a) Sample documentation or template demonstrating quality oversight body review of distribution accuracy analysis and trending.

Demonstrating Compliance: Validation Review

- (a) Evidence demonstrating quality oversight body review of distribution accuracy analysis and trending at least quarterly.
- (a) Evidence demonstrating any action plans designed to improve or correct identified problems.

FOCUS AREA: Patient Service and Communication

STANDARD P-PSC 1: Patient Information and Support

Patients and prescribers receive support and drug-related information when needed. Adverse drug events are communicated appropriately.

P-PSC 1-1: Patient Information

Upon initial fill of a prescription, the pharmacy:

a. Provides information regarding how to: [2]
    i. Access pharmacy representatives
    ii. Fill a prescription, including refills
    iii. Obtain order status and delays
    iv. Have a prescription transferred
    v. Report a suspected medication issue
b. Provides transparent financial information on: [2]
    i. The patient's out-of-pocket costs such as deductibles, co-pays, and co-insurance, as available
    ii. The cash price of the medication, upon request

Interpretive Information

- (a)(v) Suspected medication issues include counterfeit medications, errors, adverse drug events, etc.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for providing information to patients, including when the information is shared.
- (a) Sample documentation demonstrating the information provided to patients.
- (b) Document(s) describing the pharmacy's process for providing transparent financial information to patients, including when the information is shared.

Demonstrating Compliance: Validation Review

- (b) Interview with staff

P-PSC 1-2: Support Services

During business hours, the pharmacy:

a. Responds to the following types of inquiries from patients and/or prescribers: [4]
    i. Patient financial responsibilities
    ii. Whether the pharmacy is in or out of network
    iii. Prescription order status
    iv. How to submit a complaint
    v. Safe drug disposal
    vi. How to address adverse drug events
    vii. How to report suspected medication errors

Interpretive Information

- (a) Communications with the patient and provider should accommodate the diversity of the patient population, including persons with linguistic, cultural, cognitive and physical differences.
- (a) Hours of operation should be clearly specified.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for responding to inquiries from patients and/or prescribers.

Demonstrating Compliance: Validation Review

- (a) Interview with staff.

P-PSC 1-3: Adverse Drug Events

After identifying adverse drug events, the pharmacy:

a. Reports serious and unexpected adverse drug events to appropriate external entities [4]

Interpretive Information

- (a) External entities may include FDA MedWatch, Patient Safety Organizations, the provider, etc.
- (a) New FDA guidance or manufacturer requirements may derive from pharmacovigilance activities performed by pharmacies, such as aftermarket adverse drug event reporting.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for reporting serious and unexpected adverse drug events.

Demonstrating Compliance: Validation Review

- (a) Interview with staff.

STANDARD P-PSC 2: Measuring Complaints and Satisfaction

Information on patient and prescriber complaints and satisfaction is used to improve the quality of pharmacy services.

P-PSC 2-1: Patient and Prescriber Complaints

The pharmacy:

a. Measures patient and prescriber complaints [4]

b. Analyzes data and identifies performance trends for review by the quality oversight body at least quarterly on the following: [4]

   i. Patient complaints

   ii. Prescriber complaints

c. Implements action plans designed to improve or correct identified problems as needed [2]

Interpretive Information

- (b) Analysis and performance trending requires identification of quantifiable goals and monitoring progress in meeting these goals.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy measures patient and prescriber complaints.
- (b) Document(s) outlining how the pharmacy analyzes and trends patient and prescriber complaints for review by the quality oversight body at least quarterly.
- (b) Sample documentation or template demonstrating quality oversight body review of patient and prescriber complaint analysis and trending.
- (c) Document(s) outlining how the pharmacy implements action plans to improve or correct identified problems as needed.

Demonstrating Compliance: Validation Review

- (b) Evidence demonstrating quality oversight body review of patient and prescriber complaint analysis and trending at least quarterly.
- (c) Evidence demonstrating any action plans designed to improve or correct identified problems.

P-PSC 2-2: Patient and Prescriber Satisfaction

The pharmacy:

a. Measures patient and prescriber satisfaction [4]

b. Analyzes data and identifies performance trends on patient satisfaction for review by the quality oversight body at least once per calendar year [4]

c. Implements action plans designed to improve or correct identified problems as needed [2]

Interpretive Information

- (b) Analysis and performance trending requires identification of quantifiable goals and monitoring progress in meeting these goals.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy measures patient and prescriber satisfaction.
- (b) Document(s) outlining how the pharmacy analyzes and trends patient satisfaction for review by the quality oversight body at least once per calendar year.
- (b) Sample documentation or template demonstrating quality oversight body review of patient satisfaction analysis and trending.
- (c) Document(s) outlining how the pharmacy implements action plans to improve or correct identified problems as needed.

Demonstrating Compliance: Validation Review

- (b) Evidence demonstrating quality oversight body review of patient satisfaction analysis and trending at least once per calendar year.
- (c) Evidence demonstrating any action plans designed to improve or correct identified problems.

STANDARD P-PSC 3: Communication Process and Monitoring

Patient communications accommodate the diversity of the population. All communications are handled in a timely manner. Clinical communications are handled by a clinician.

P-PSC 3-1: Patient Communications

The pharmacy:

a. Accommodates the diversity of the patient population during communications, including persons with: [8]
    i. Linguistic differences
    ii. Cultural differences
    iii. Cognitive impairments
    iv. Physical impairments
b. Accommodates the patient's preferred outreach method [L]

Interpretive Information

- (a)(i) Accommodations for language differences may include use of a language line, bilingual staff, certified translators, translation of communications materials, etc.
- (a)(ii) Accommodations for cultural differences may include assisting patients with cultural dietary restrictions, training staff on cultural sensitivities, etc.
- (a)(iii) Accommodations for cognitive impairments may include use of plain-language, communication with a caregiver, etc.
- (a)(iv) Accommodations for physical impairments may include use of telecommunication tools to support patients who are deaf, hearing impaired, or speech-impaired, Braille or large font print for the vision-impaired, etc.
- (b) Accommodating the patient's preferred outreach method enhances patient participation in their care.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy accommodates the diversity of the patient population during communications.
- (b) Document(s) outlining how the pharmacy accommodates the patient's preferred outreach method.
    - If the organization chooses not to meet this leading indicator, submit a statement to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a)-(b) Interview with staff.

P-PSC 3-2: Telephone Performance

The pharmacy:

a. Sustains a quarterly telephone performance metric of average abandonment rate of 5% or less [4]

b. Sustains a quarterly telephone performance metric of at least 80% of calls answered by a live person within 30 seconds [4]

c. Analyzes data and identifies performance trends on telephone performance metrics for review by the quality oversight body at least quarterly [4]

d. Implements action plans designed to improve or correct identified problems as needed [2]

Interpretive Information

- (a) Abandonment rate is defined as the percentage of calls that were abandoned by a caller after being placed in the Automatic Call Distribution queue and before being answered by a live organization representative.
- (a) Calls are still considered abandoned if the caller leaves a voice mail message or accepts a call-back.
- (a) Abandonment rate is NOT measured as the percentage of calls that disconnect after 30 seconds when an individual (live person) would have answered the call.

Demonstrating Compliance: Desktop Review

- (a) Document(s) requiring the pharmacy to sustain telephone performance metrics for average abandonment rate.
- (b) Document(s) requiring the pharmacy to sustain telephone performance metrics for percent of calls answered by a live person within 30 seconds.
- (c) Document(s) outlining how the pharmacy analyzes and reviews telephone performance for review by the quality oversight body at least quarterly.
- (c) Sample documentation or template demonstrating quality oversight body review of telephone performance analysis and trending.
- (d) Document(s) outlining how the pharmacy implements action plans to improve or correct identified problems as needed.

Demonstrating Compliance: Validation Review

- (a) Guided review of quarterly abandonment rate reports.
- (b) Guided review of quarterly percentage of calls answered within 30 seconds reports.
- (c) Evidence demonstrating quality oversight body review of telephone performance analysis and trending at least quarterly.
- (d) Evidence demonstrating any action plans designed to improve or correct identified problems.

P-PSC 3-3: Non-Telephonic Communications

The pharmacy:

a. Addresses timely response of non-telephonic communications from a patient or prescriber [4]

b. Supports bi-directional electronic communication between the patient and the pharmacy [L]

Interpretive Information

- (b) Bi-directional electronic communication may include secure text message platforms, patient portals, etc. This does not include telephonic communications, facsimile, e-mail or interactive voice response (IVR) systems.
- (b) Bi-directional electronic communications may provide another opportunity to accommodate patient preferred outreach methods.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy addresses timely response of non-telephonic communications, including which non-telephonic methods of communication are used and the response time for each.
- (b) Document(s) outlining how the pharmacy supports bi-directional electronic communications between the patient and the pharmacy.
    - If the organization chooses not to meet this leading indicator, submit a statement to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a)-(b) Interview with staff.

P-PSC 3-4: Clinical Communication Services

The pharmacy:

a. Provides clinical communications such that: [8]
    i. Clinical calls are handled 24 hours a day 7 days a week
    ii. All clinical communications are answered in a timely manner
    iii. Counseling is provided to patients as needed and upon request
    iv. Communications are escalated as needed to a clinician

Interpretive Information

- (a)(ii) The organization implements criteria for determining the urgency of a clinical call and the appropriate time frame for a response given the level of urgency.
- (a)(iv) An escalation matrix should be used to define when communications need to be escalated to a clinician.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy provides clinical communications.

Demonstrating Compliance: Validation Review

- (a) Interview with staff.
- (a) Interview with clinical leadership.

FOCUS AREA: Patient Management

STANDARD PM 1: Patient Management Program Structure

The organization maintains a patient management program description. [M]

PM 1-1: Program Structure

The pharmacy:

a. Outlines the scope of services within the patient management program description, to include:

   i. Clinical processes and workflows specific to each drug and/or disease state based on medical or scientific evidence and/or demonstrated clinical practice guidelines/protocols

   ii. Goals and objectives

Interpretive Information

- (a) Services provided through the patient management program and incorporated within the clinical processes and workflows include assessments, education, clinical interventions, etc.
- (a) Clinical processes and workflows are specific to the drug and/or disease state and based on evidence.

Demonstrating Compliance: Desktop Review

- (a) Document(s) defining the scope of services to include clinical processes and workflows specific to each drug and/or disease state based on evidence and the goals and objectives of the program.

Demonstrating Compliance: Validation Review

- (a) Interview with clinical leadership.

STANDARD PM 2: Patient Management Program Overview

The organization's patient management program has appropriate oversight and is available to all patients receiving a specialty medication. The program is designed to provide quality patient care.

PM 2-1: Program Oversight

The pharmacy:

a. Develops the patient management program with oversight by the clinical oversight body [4]

b. Implements the patient management program to follow the specific drug and/or disease state clinical processes and workflows with: [8]

   i. Oversight by a pharmacist or qualified health professional

   ii. Provision of clinical services by a pharmacist or other qualified health professional

   iii. Criteria for when information gathered by a non-clinician or system must be escalated for timely review by a clinician

c. Demonstrates that the patient management program is reviewed, approved and updated, as needed, by the clinical oversight body at least annually, including the drug and/or disease state specific clinical processes and workflows [4]

Interpretive Information

- (a) The clinical oversight body is made up of qualified health professionals including at least one pharmacist.
- (b) A general clinical process or workflow for all drugs and/or disease states is not appropriate.
- (b)(i)-(b)(ii) "Other qualified health professionals" typically include registered nurses and physicians.
  - Pharmacy technicians, pharmacy interns, community health workers and licensed practical nurses (LPNs) are generally not qualified to provide clinical services within the patient management (drug management) program.
  - Exceptions may apply based on state laws and regulations. Documentation of compliance with laws and regulations, including appropriate supervision, is required when there is an exception. Appropriate supervision considers capacity allowances per laws and regulations as well.

- (b)(ii) Clinical services requiring a pharmacist or other qualified health professional may include initial assessments, education, reassessments, clinical interventions, etc.
- (b)(ii) If a non-qualified health professional gathers clinical data for the program there must be evidence that the data was evaluated or interpreted by an appropriate qualified health professional.

Demonstrating Compliance: Desktop Review

- (a) Evidence of the pharmacy developing the patient management program with oversight by the clinical oversight body.
- (b) Document(s) outlining how the pharmacy implements the patient management program to follow the drug and/or disease state clinical processes and workflows.
- (c) Document(s) outlining how the clinical oversight body reviews and updates the patient management program at least annually.
- (c) Sample documentation or template demonstrating review and approval of the patient management program by the clinical oversight body.

Demonstrating Compliance: Validation Review

- (b) Random sample of patient files to verify the patient management program follows the specific drug and/or disease state clinical processes and workflows.
- (c) Evidence or template demonstrating annual review and approval of the patient management program by the clinical oversight body.

PM 2-2: Patient Participation

The pharmacy:

a. Provides patient management program services to all patients receiving a specialty prescription [8]

b. Encourages patients to participate in their care and the services provided by the patient management program [4]

c. Documents when a patient opts-out of the patient management program [2]

Interpretive Information

- (c) Provider management of patients may be appropriate for select specialty patients when policies and procedures clearly document the exception process.

Demonstrating Compliance: Desktop Review

- (a) Document(s) requiring the pharmacy to provide patient management program services to all patients receiving a specialty prescription.
- (b) Document(s) outlining how the pharmacy encourages patients to participate.
- (c) Document(s) outlining how the pharmacy documents when a patient opts-out of the patient management program.

Demonstrating Compliance: Validation Review

- (a) Random sample of patient files to verify all patients receiving a specialty prescription are enrolled in the patient management program or have opt-out documentation.
- (b) Interview with staff.
- (c) Random sample of patient files to verify documentation when a patient opts-out of the patient management program.

PM 2-3: Documentation

The pharmacy:

a. Documents all patient management information in a consistent location [2]

Interpretive Information

- (a) Elements of documentation include assessments, interventions, and education.
- (a) "Consistent location" means all relevant pharmacy staff know where specific information should be located, even if multiple systems are used to document information.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for documenting patient management information.

Demonstrating Compliance: Validation Review

- (a) Random sample of patient files to verify patient management information is documented in a consistent manner.

STANDARD PM 3: Program Disclosures

The patient management program discloses the rights and responsibilities of the program to all patients.

PM 3-1: Rights and Responsibilities

Upon enrollment, the pharmacy:

a. Shares with the patient their rights as they relate to the patient management program, to include the right to: [4]
    i. Have personal health information shared only in accordance with state and federal law
    ii. Identify the program's staff members, including their job title, and to speak with a staff member's supervisor if requested
    iii. Speak to a health professional
    iv. Receive information about the patient management program
    v. Decline participation, or disenroll, at any point in time
b. Shares with the patient their responsibilities as they relate to the patient management program, to include the responsibility to: [4]
    i. Give accurate clinical and contact information and provide notification when there is a change
    ii. Notify the treating prescriber of their participation in the patient management program

Interpretive Information

- Intentionally left blank.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy shares patient rights as they relate to the patient management program with patients
- (a) Evidence demonstrating information shared with patient on their rights as they relate to the patient management program.
- (b) Document(s) outlining how the pharmacy shares patient responsibilities as they relate to the patient management program with patients
- (b) Evidence demonstrating information shared with patient on their responsibilities as they relate to the patient management program.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

STANDARD PM 4: Clinical Assessments and Interventions

The patient management program services include clinical assessments and interventions that utilize drug and/or disease state specific clinical processes and workflows.

PM 4-1: Initial Assessments

The pharmacy:

a. Conducts an initial patient assessment prior to the first fill of the medication to determine the appropriateness of the therapy, given the patient's: [8]
    i. Diagnosis
    ii. Medication list
    iii. Comorbidities
    iv. Allergies
    v. Medical history
    vi. Patient's ability to self-administer medication
    vii. Therapeutic goals based on possible outcomes of therapy

Interpretive Information

- (a) Initial assessments are incorporated into the drug and/or disease state specific clinical processes and workflows. A general assessment for all drugs and/or disease states is not appropriate.
- (a) Initial assessments are completed by a pharmacist or other qualified health professional.
- (a) If a non-clinician gathers clinical data for the program there must be evidence that the data was evaluated or interpreted by appropriate clinical staff.
- (a) Initial assessment information may be obtained through the electronic medical record, provider notes, conversation(s) with the provider and other health care workers, conversation(s) with the patient, etc.
- (a) Even when full accreditation or certification is achieved, if this standard is identified as "Not Met," a follow-up validation review will occur within six (6) months to verify full compliance.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for conducting initial patient assessments.
- (a) Sample documentation or a template demonstrating an initial patient assessment.

Demonstrating Compliance: Validation Review

- (a) Random sample of patient files to verify implementation and documentation of the initial assessment process.

PM 4-2: Reassessments

The pharmacy:

a. Conducts periodic reassessments, no more than 12 months from the previous assessment, to determine if the medication remains appropriate given the patient's: [8]

   i. Current medication list

   ii. Experience of adverse reactions to the medication

   iii. Adherence to therapy

   iv. Progress toward achieving patient's therapeutic goals based on outcomes of therapy

Interpretive Information

- (a) "Periodic" is determined by the organization based on the clinical processes and workflows for each drug and/or disease state.
- (a) Reassessments are incorporated into the drug and/or disease state specific clinical processes and workflows. A general assessment for all drugs and/or disease states is not appropriate.
- (a) Reassessments are completed by a pharmacist or other qualified health professional.
- (a) If a non-clinician gathers clinical data for the program there must be evidence that the data was evaluated or interpreted by appropriate clinical staff.
- (a) Even when full accreditation or certification is achieved, if this standard is identified as "Not Met," a follow-up validation review will occur within six (6) months to verify full compliance.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for conducting patient reassessments.
- (a) Sample documentation or a template demonstrating a patient reassessment.

Demonstrating Compliance: Validation Review

- (a) Random sample of patient files to verify implementation and documentation of the reassessment process.

PM 4-3: Clinical Interventions

The pharmacy:

a. Makes and documents targeted clinical interventions based on patient assessments and as needed [4]

b. Documents outcome(s) for clinical interventions [4]

c. Analyzes and identifies trends on clinical intervention outcomes data for review by the clinical oversight body at least quarterly [2]

Interpretive Information

- (a) Clinical interventions are made by a pharmacist or other qualified health professional.
- (b) Clinical intervention outcomes are what happened as a result of the clinical intervention.
- (b) Clinical intervention outcomes may include prevention of hospitalization, prevention of an adverse drug event, discontinuation of inappropriate therapy, improved therapy adherence, improved therapy effectiveness, etc.
- (c) Clinical intervention outcomes data are aggregate outcomes, not individual patient outcomes.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy makes and documents targeted clinical interventions.
- (b) Document(s) outlining how the pharmacy documents outcome(s) for clinical interventions.
- (c) Document(s) outlining how the pharmacy analyzes and reviews clinical intervention outcome(s) for review by the clinical oversight body at least quarterly.
- (c) Sample documentation or template demonstrating clinical oversight body review of clinical intervention outcome(s) analysis and trending.

Demonstrating Compliance: Validation Review

- (a) Random sample of patient files to review clinical interventions made and documented.
- (c) Evidence demonstrating clinical oversight body review of clinical intervention outcome(s) analysis and trending at least quarterly.

STANDARD PM 5: Education and Support

The patient receives education to promote safe and effective medication use.

PM 5-1: Education Requirements

The pharmacy:

a. Provides patient and/or caregiver education prior to the first use of medication and includes: [8]
    i. Expectations and possible outcomes of therapy
    ii. Proper use, administration and duration of therapy
    iii. Side effects, including prevention, minimization, and management
    iv. Missed dose management
    v. Contraindications and safety precautions
    vi. Safe handling, storage, and disposal
    vii. When to report new or changed medications
    viii. Vaccinations, as appropriate
b. Provides education as needed and upon request from the patient and/or caregiver, physician, or other health care provider [4]
c. Includes educational, community and advocacy resources as appropriate [4]

Interpretive Information

- (a) Education should be offered using the most appropriate method to meet the patient's communication needs.
- (a) Education is incorporated into the drug and/or disease state specific clinical processes and workflows.
- (a)(vii) New or changed medications may include over-the-counter medications, herbals, supplements, etc.
- (a)-(c) Communications with the patient and/or caregiver should accommodate the diversity of the patient population, including persons with linguistic, cultural, cognitive and physical differences.
- (a) Even when full accreditation or certification is achieved, if this standard is identified as "Not Met," a follow-up validation review will occur within six (6) months to verify full compliance.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for educating patients prior to first use of the medication.
- (b) Document(s) requiring the pharmacy to provide education as needed and upon request.
- (c) Document(s) outlining how the pharmacy includes educational, community, and advocacy resources within patient education as appropriate.

Demonstrating Compliance: Validation Review

- (a) Random sample of patient files to verify that education was provided and documented prior to first use of the medication.
- (b)-(c) Interview with staff.

STANDARD PM 6: Care Team Collaboration

Patient management information is clearly communicated to health care providers. The patient management program supports transitions of care.

PM 6-1: Coordination of Care

The pharmacy:

a. Communicates with prescribers and other health care providers regarding individual patient issues [8]

b. Supports transitions of care [4]

c. Communicates issues regarding social determinants of health, when identified, to the appropriate entity [4]

d. Shares applicable patient data with other health care providers and stakeholders to promote comprehensive patient care [L]

Interpretive Information

- (c) Social determinants of health may include financial, transportation, employment, physical environment, social support, food security, etc.

Demonstrating Compliance: Desktop Review

- (a) Document(s) outlining how the pharmacy communicates regarding individual patient issues.
- (b) Document(s) outlining how the pharmacy supports transitions of care
- (c) Document(s) outlining how the pharmacy communicates issues associated with social determinants of health.
- (d) Document(s) outlining how the pharmacy shares applicable patient data with other healthcare providers and stakeholders.
    - If the organization chooses not to meet this leading indicator, submit a statement to that effect so this standard may be identified as not applicable.

Demonstrating Compliance: Validation Review

- (a)-(d) Interview with staff.

STANDARD PM 7: Program Evaluation and Review

The patient management program is evaluated at least annually to improve value, effectiveness and patient care.

PM 7-1: Annual Patient Management Program Evaluation

The pharmacy:

a. Evaluates the patient management program at least annually: [4]
    i. With oversight by the clinical oversight body,
    ii. For value and effectiveness
    iii. Including the goals and objectives of the program
b. Reviews at least the following program data within the patient management program evaluation: [4]
    i. Clinical metrics
    ii. Financial metrics
    iii. Health related quality of life metrics
    iv. Clinical intervention outcomes
c. Demonstrates that the clinical oversight body makes recommendations and updates to the patient management program based on the evaluation [4]

Interpretive Information

- (a) The patient management program evaluation can be used to determine internal value and effectiveness of the program and/or to demonstrate the value and effectiveness of the program to external parties.
- (b)(i) Clinical metrics may include laboratory values, health screenings, adherence measurement, resolution of health condition, patient pain level, etc.
- (b)(ii) Financial metrics may include savings from Patient Assistance Programs, projected medical savings due to avoided hospitalizations or MD office visits, projected savings from promoting adherence to therapy, savings from factor assay management, savings from consolidation of duplicative therapy or polypharmacy, etc.
- (b)(iii) Health related quality of life metrics may include quality of life assessments, quality adjusted life years assessments, measurements of self-care, etc.
- (b)(iv) Clinical intervention outcomes are what happened as a result of the clinical intervention.

- (b)(iv) Clinical intervention outcomes may include prevention of hospitalization, prevention of an adverse drug event, discontinuation of inappropriate therapy, improved therapy adherence, improved therapy effectiveness, etc.

Demonstrating Compliance: Desktop Review

- (a) Document(s) describing the pharmacy's process for evaluating the patient management program.
- (b) Document(s) defining the program data reviewed within the patient management program evaluation.
- (a)-(b) Sample documentation or template demonstrating a patient management program evaluation, including the program data reviewed within the evaluation.
- (c) Document(s) outlining how the clinical oversight body makes recommendations and updates to the patient management program based on the evaluation.
- (c) Sample documentation or template demonstrating a patient management program recommendation.

Demonstrating Compliance: Validation Review

- (a) Evidence demonstrating patient management program evaluation at least annually.
- (b) Evidence demonstrating patient management program evaluation at least annually, including the program data reviewed within the evaluation.
- (c) Evidence demonstrating patient management program recommendation at least annually.

Focus Area RPT: Reporting Performance Measures to URAC

Standard RPT 1: Reporting Mandatory Performance Measures to URAC

Mandatory measures reporting is used to evaluate and improve the quality and efficiency of health services. [M]

RPT 1-1: Reporting Mandatory Performance Measures to URAC

Report data to URAC on all applicable Mandatory performance measures

Interpretive Information

- Beginning the calendar year after URAC accreditation is awarded, organizations should start collecting mandatory measures and be able to produce their first set of reports on measures collected between January 1 and December 31. This calendar year is the organization's first collection period. The measure submission period begins on July 1st of the following year and measures must be submitted by no later than September 30th of the year following the first measurement period. Measures are then reported annually to URAC while the organization is accredited.
- Updates to measures will be made available in the fourth quarter of each year. Accredited organizations are required to adhere to the most current set of measure specifications issued by URAC for each reporting year.
    - IMPORTANT NOTE: The most up-to-date measures specifications are available for the organization's download through AccreditNet®. The measures specifications contain guidance regarding reporting and requirements for each measure.
- Organizations are required to submit all Mandatory measures on an annual basis, pursuant to the RPT-1 standard, when included within their accreditation product. This standard has a mandatory compliance rating; therefore, failure to submit mandatory measures on an annual basis adversely affects an organization's accreditation status.

Demonstrating Compliance: Desktop Review

- Signed attestation indicating that the organization will upload and submit data to URAC or a URAC designee on a URAC-specified platform.
    - The Measure Attestation is available in AccreditNet® or by contacting your Client Relations Manager.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.

Standard RPT 2: Reporting Exploratory Performance Measures to URAC

Exploratory measures reporting is used to provide insight into emergent industry trends and practices. [L]

RPT 2-1: Reporting Exploratory Performance Measures to URAC

Report data to URAC on all applicable Exploratory performance measures

Interpretive Information

- Beginning the calendar year after URAC accreditation is awarded, organizations should start collecting mandatory measures and be able to produce their first set of reports on measures collected between January 1 and December 31. This calendar year is the organization's first collection period. The measure submission period begins on July 1st of the following year and measures must be submitted by no later than September 30th of the year following the first measurement period. Measures are then reported annually to URAC while the organization is accredited.
- Updates to measures will be made available in the fourth quarter of each year. Accredited organizations are required to adhere to the most current set of measure specifications issued by URAC for each reporting year.
    - IMPORTANT NOTE: The most up-to-date measures specifications are available for the organization's download through AccreditNet®. The measures specifications contain guidance regarding reporting and requirements for each measure.
- Exploratory measures are not required for annual reporting, per the RPT-2 standard. Reporting, however, is strongly encouraged – even if supplying only responses to background questions. URAC uses this information to facilitate the measurement development process based on the responses to glean a better understanding of the appropriateness and ease of reporting. In future versions of the measures, exploratory measure may evolve into mandatory measures as consensus builds on appropriate reporting specifications for the measures.

Demonstrating Compliance: Desktop Review

- Signed attestation indicating that the organization will upload and submit data to URAC or a URAC designee on a URAC-specified platform.
    - The Measure Attestation is available in AccreditNet® or by contacting your Client Relations Manager.

Demonstrating Compliance: Validation Review

- Compliance determined on Desktop Review.